

## Message Text

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EUR/CE:JHURLEY  
EUR/WE:VBROD  
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-----031206 010212Z /70

P 312159Z MAY 78  
FM SECSTATE WASHDC  
TO AMCONSUL FRANKFURT PRIORITY  
AMEMBASSY PARIS PRIORITY  
AMEMBASSY LONDON PRIORITY  
AMEMBASSY BERN PRIORITY  
USMISSION GENEVA PRIORITY  
AMEMBASSY ROME PRIORITY

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FRANKFURT FOR GAO EDER

E.O. 11652: N/A

TAGS: AGAO, ECSM

SUBJECT:GAO REVIEW: "NEW DRUG DEVELOPMENT AND APPROVAL  
PROCESS"

1. THE GAO HAS INFORMED THE DEPARTMENT THAT IT PLANS TO UNDERTAKE SUBJECT REVIEW IN ADDRESSEE COUNTRIES IN PURSUANCE OF A CONGRESSIONAL REQUEST. DATES OF VISIT SUBJECT TO POST'S CONCURRENCE.
2. THE GAO WANTS TO COMPARE THE REQUIREMENTS, POLICIES,  
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AND PRACTICES USED BY OTHER COUNTRIES TO REGULATE NEW DRUG DEVELOPMENT TO DETERMINE WHETHER NEW DRUGS ARE INTRODUCED MORE RAPIDLY THAN IN THE U.S. A SIGNIFICANT PORTION OF THIS WORK WILL ENTAIL A COMPARISON OF THE UNITED STATES' DRUG REGULATORY PROCESS WITH THE REGULATORY PROCESSES OF CERTAIN EUROPEAN COUNTRIES. THE GAO HAS JUST COMPLETED A REVIEW OF AND DEVELOPED INFORMATION ON THE CANADIAN DRUG

APPROVAL SYSTEM.

3. THE BASIC GAO OBJECTIVES IN THIS REVIEW WILL BE TO OBTAIN INFORMATION ON THE RELATIONSHIP BETWEEN THE HOST COUNTRY'S LEGISLATIVE BODY AND ITS DRUG REGULATORY AGENCY; THE LEGAL REQUIREMENTS FOR NEW DRUG APPROVALS AND THEIR IMPLEMENTING PROCEDURES, AND THE ADVANTAGES, IF ANY, OF FOREIGN DRUG APPROVAL PROCESSES OVER THOSE OF THE UNITED STATES. THE GAO ALSO PLANS TO OBTAIN THE OPINIONS OF FOREIGN REGULATORY AND PHARMACEUTICAL OFFICIALS, MEDICAL EXPERTS AND MEMBERS OF MEDICAL ASSOCIATIONS CONCERNING IMPROVEMENTS THAT COULD BE MADE TO THE DRUG APPROVAL PROCESS. THE GAO WILL ALSO BE INTERESTED IN SECURING INFORMATION ON THEIR RATE OF NEW DRUG DEVELOPMENT, THE COMPOSITION OF THEIR WORKLOAD AND PRIORITY SYSTEMS, THE LENGTH OF TIME REQUIRED FOR DRUG APPROVAL, THERAPEUTICALLY IMPORTANT DRUGS AVAILABLE OVERSEAS BUT NOT IN THE UNITED STATES, AND INCIDENCE OF ADVERSE REACTIONS AND DRUG RECALLS.

4. THE GAO WOULD APPRECIATE ADDRESSEE POSTS INFORMING REGULATORY OFFICIALS WHO ARE THE EQUIVALENT OF THE U.S. FOOD AND DRUG ADMINISTRATION'S DIRECTOR OF BUREAU OF DRUGS OF THIS REVIEW AND PLANNED VISIT. AFTER CONTACTING THESE REGULATORY OFFICIALS, PLEASE FORWARD TO DEPARTMENT THEIR NAMES AND TELEPHONE NUMBERS SO THAT GAO WASHINGTON CAN UNCLASSIFIED

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MAKE FOLLOWUP CONTACTS TO WORK OUT DETAILS OF THE VISIT. IN EUROPE, AS WAS THE CASE IN CANADA, THE GAO'S PRINCIPAL OBJECTIVE WILL BE TO BRIEFLY MEET WITH SENIOR REGULATORY OFFICIALS TO OBTAIN AN OVERVIEW OF THEIR SYSTEM AND SPEND THE MAJOR PART OF THE TIME WITH THE PERSONNEL INVOLVED IN THE DAY-TO-DAY OPERATIONS OF THE DRUG APPROVAL PROCESS AS WELL AS WITH MEMBERS OF THE MEDICAL PROFESSION.

5. THE POST'S ASSISTANCE IS ALSO REQUESTED TO DESIGNATE AND INFORM DEPARTMENT THE NAME AND TELEPHONE NUMBER OF PROJECT OFFICER WHO WILL WORK WITH THE GAO TEAM IN SETTING UP MEETINGS WITH APPROPRIATE GOVERNMENT OFFICIALS AND REPRESENTATIVES OF BUSINESS FIRMS IN ACCORDANCE WITH THE DATES AVAILABLE FOR MEETINGS SHOWN IN PARAGRAPH 6. THE FOLLOWING FOREIGN OFFICIALS HAVE BEEN IDENTIFIED TO THE GAO AS POSSIBLE CONTACTS:

FRANCE

MONSIEUR LE DIRECTEUR DE LA PHARMACIE  
ET DU MEDICAMENT  
MINISTERE DE LA SANTE PUBLIQUE

9 AVENUE LOWENDAL  
75 PARIS 7E FRANCE

UNITED KINGDOM

DR. JOHN P. GRIFFIN  
SENIOR PRINCIPAL MEDICAL OFFICER  
DEPARTMENT OF HEALTH AND SOCIAL SECURITY  
FINSBURY SQUARE HOUSE  
33-37 A FINSBURY SQUARE  
LONDON EC2A 1PP  
LORD COHEN OF BIRKENHEAD  
CHAIRMAN, COMMITTEE ON SAFETY OF MEDICINE

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SWITZERLAND

VON DR. P. FISCHER  
MONSIEUR LE DIRECTEUR  
OFFICE INTERCANTONAL DE CONTROLE DES MEDICAMENTS  
8 ERLACHSTRASSE  
3000 BERNE 9  
TELEPHONE 031/23 01 05

ITALY

MR. VANNUGLI  
CHIEF OF INTERNATIONAL RELATIONS  
MINISTER OF HEALTH

PROFESSOR DUILIO POGGIOLINI  
DIRETTORE GENERALE DEL SERVIZIO FARMACEUTICO  
MINISTERO DELLA SANITA  
00100 ROME, ITALY  
TELEPHONE 595863

CONTACTS WITH PHARMACEUTICAL ASSOCIATIONS AND PRIVATE  
MEDICAL GROUPS WILL BE ARRANGED BY THE GAO THROUGH THE  
PHARMACEUTICAL MANUFACTURERS ASSOCIATION IN THE  
UNITED STATES.

FOR GENEVA: THE MISSION'S ASSISTANCE IN WORKING UP A  
SCHEDULE FOR DR. MURRAY GRANT AND MESSRS. LAURIE AND  
JOJOKIAN TO MEET WITH THE FOLLOWING NAMED PERSONNEL OF THE  
WORLD HEALTH ORGANIZATION ON EITHER JULY 17 OR 18 WILL BE  
APPRECIATED.

DR. V. FATTURUSSO, DIRECTOR, DIVISION OF PROPHYLACTIC,  
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DIAGNOSTIC AND THERAPEUTIC SUBSTANCES

DR. CHEN WEN-CHIEN, ASSISTANT DIRECTOR, (SAME DIVISION)

DR. FRANK PERKINS, DIRECTOR, BIOLOGICAL UNIT

6. THE GAO PLANS TO HAVE TWO TEAMS CONSISTING OF TWO PERSONS TO CONDUCT THE REVIEWS IN EUROPE; TWO FROM THE UNITED STATES AND TWO FROM THE GAO EUROPEAN BRANCH OFFICE

IN FRANKFURT. EACH TEAM WILL SPEND BETWEEN 2 AND 7 DAYS IN EACH COUNTRY DURING THE 5-WEEK PERIOD FROM JUNE 26 TO JULY 28, 1978 IN ACCORDANCE WITH THE SCHEDULE BELOW:

TEAM NUMBER 1 LEAD BY MR. RONALD A. VIEREGGE PLUS ONE OTHER TEAM MEMBER TO BE NAMED.

| DATES          | COUNTRY                          | FOR MEETINGS    |
|----------------|----------------------------------|-----------------|
| JUNE 25        | ARRIVE FRANKFURT                 |                 |
| JUNE 26-28     | FRANKFURT, (WITH GAO)            |                 |
| JUNE 28        | ARRIVE PARIS (P.M.)              |                 |
| JUNE 29-JULY 1 | FRANCE                           | JUNE 29-30      |
| JULY 1         | ARRIVE LONDON (P.M.)             |                 |
| JULY 2-11      | UNITED KINGDOM                   | JULY 3-7, 10-11 |
| JULY 11        | ARRIVE FRANKFURT                 |                 |
| JULY 12-15     | FRANKFURT, GERMANY<br>(WITH GAO) |                 |

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|            |                    |            |
|------------|--------------------|------------|
| JULY 16    | ARRIVE BERN (P.M.) |            |
| JULY 16-21 | SWITZERLAND        | JULY 17-21 |
| JULY 22    | ARRIVE ROME (P.M.) |            |
| JULY 22-25 | ITALY              | JULY 24-25 |

JULY 25 ARRIVE BY AIR FRANKFURT  
(P.M.)

JULY 26-28 FRANKFURT (WITH GAO)

7. IN ADDITION TO THE TWO-MAN TEAMS MENTIONED IN PARA 6  
SUPRA, THE FOLLOWING GAO REPRESENTATIVES WILL TRAVEL  
ON SEPARATE ITINERARY AND PARTICIPATE IN SOME OF THE  
VISITS AS OUTLINED BELOW:

A) DR. MURRAY GRANT, MEDICAL ADVISOR, GAO/WASHINGTON,  
WILL BE MEETING WITH MEDICAL EXPERTS AND MEMBERS OF  
CONCERNED ASSOCIATIONS:

| DATES | COUNTRY |
|-------|---------|
|-------|---------|

|              |                       |
|--------------|-----------------------|
| JUNE 26 - 28 | FRANKFURT, (WITH GAO) |
|--------------|-----------------------|

|         |                   |
|---------|-------------------|
| JUNE 29 | DRIVING TO NORWAY |
|---------|-------------------|

|         |        |
|---------|--------|
| JUNE 30 | NORWAY |
|---------|--------|

|            |               |
|------------|---------------|
| JULY 3 - 4 | SWEDEN BY AIR |
|------------|---------------|

|        |               |
|--------|---------------|
| JULY 5 | ARRIVE LONDON |
|--------|---------------|

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|            |        |
|------------|--------|
| JULY 5 - 7 | LONDON |
|------------|--------|

|        |                      |
|--------|----------------------|
| JULY 8 | ARRIVE BY AIR SWEDEN |
|--------|----------------------|

|              |           |
|--------------|-----------|
| JULY 10 - 11 | AMSTERDAM |
|--------------|-----------|

|              |                               |
|--------------|-------------------------------|
| JULY 12 - 14 | FRANKFURT, GERMANY (WITH GAO) |
|--------------|-------------------------------|

|              |              |
|--------------|--------------|
| JULY 17 - 18 | GENEVA (WHO) |
|--------------|--------------|

|              |        |
|--------------|--------|
| JULY 19 - 21 | BERLIN |
|--------------|--------|

|              |      |
|--------------|------|
| JULY 24 - 25 | BONN |
|--------------|------|

|              |                      |
|--------------|----------------------|
| JULY 26 - 28 | FRANKFURT (WITH GAO) |
|--------------|----------------------|

B) MR. WILLIAM LAURIE, AUDIT MANAGER, GAO/DETROIT  
REGIONAL OFFICE

|        |               |
|--------|---------------|
| JULY 9 | ARRIVE LONDON |
|--------|---------------|

JULY 10 - 11 ENGLAND

JULY 11 ARRIVE FRANKFURT

JULY 12 - 15 FRANKFURT (WITH GAO)

JULY 16 ARRIVE GENEVA

JULY 17 - 18 GENEVA (WHO)

JULY 19 - 22 ARRIVE BERLIN

DATES COUNTRY

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JULY 23 - 25 BONN

JULY 26 - 28 FRANKFURT (WITH GAO)

C) MR. ALBERT B. JOJOKIAN, ASSISTANT DIRECTOR, HUMAN  
RESOURCES DIVISION, GAO/WASHINGTON

JULY 11 ARRIVE FRANKFURT

JULY 12 - 15 FRANKFURT (WITH GAO)

JULY 16 ARRIVE BERN

JULY 16 - 21 BERN

JULY 22 ARRIVE ROME (P.M.)

JULY 22 - 25 ITALY

JULY 25 ARRIVE BY AIR FRANKFURT (P.M.)

JULY 26 - 28 FRANKFURT (WITH GAO)

8. EXCEPT FRANKFURT, WHERE GAO REGIONAL OFFICE WILL  
HANDLE HOTEL REQUIREMENTS, THE GAO WOULD APPRECIATE EACH  
POST RESERVING HOTEL ACCOMMODATIONS AT REASONABLY  
PRICED HOTEL IN ACCORDANCE WITH THE ITINERARIES LISTED  
IN PARAGRAPHS 6 AND SUB-PARAGRAPHS B) AND C) OF PARA 7.  
DR. GRANT WILL MAKE HIS OWN HOTEL ARRANGEMENTS. PLEASE  
CONFIRM RESERVATIONS TO THE DEPARTMENT AND INFO  
FRANKFURT FOR GAO.

9. NAMES OF REMAINING TEAM MEMBERS AND SECURITY  
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CLEARANCE AS WELL AS TRAVEL SCHEDULES WILL BE PROVIDED BY SEPTTEL FROM GAO FRANKFURT. GAO REPRESENTATIVES WILL MAKE THEIR OWN LOCAL TRANSPORTATION ARRANGEMENTS.

10. DEPARTMENT CERTIFIES THAT MESSRS. VIEREGGE, HUDAK, LAURIE AND JOJOKIAN GAO PERSONNEL HOLD CURRENT TOP SECRET SECURITY CLEARANCE. DR. GRANT HAS A SECRET CLEARANCE.

11. THE GAO IS AWARE THAT CONTACTS WITH FOREIGN OFFICIALS ARE AT THE DISCRETION OF THE AMBASSADOR, TO BE ARRANGED FOR BY THE EMBASSY AND EMBOFF TO ACCOMPANY, IF FEASIBLE.

12. GAO TEAM MEMBERS WILL BE PLEASED TO BRIEF THE AMBASSADOR OR APPROPRIATE EMBASSY OFFICER ON THE RESULTS OF VISITS, IF DESIRED. PLEASE ADVISE.

13. DEPARTMENT WISHES TO COOPERATE WITH THE GAO IN ACCORDANCE WITH 4 FAM 930-934. ANY QUESTIONS OR PROBLEMS THAT ARISE DURING THE COURSE OF THE REVIEW SHOULD BE REFERRED TO THE DEPARTMENT. CHRISTOPHER

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## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01 jan 1994  
**Channel Indicators:** n/a  
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**Concepts:** GAO AUDITS, DRUG PREPARATION, FOOD & DRUG REGULATIONS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Draft Date:** 31 may 1978  
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**Disposition Action:** n/a  
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**Subject:** GAO REVIEW: \"NEW DRUG DEVELOPMENT AND APPROVAL PROCESS\"  
**TAGS:** AGAO, ECSM  
**To:** FRANKFURT PARIS MULTIPLE  
**Type:** TE  
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